DEPARTMENT OF H. LTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD

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Dean A. Sommer
Cheese and Food Technologist
Wisconsin Center for Dairy Research
1605 Linden Drive
Babcock Hall
Madison, Wisconsin 53706

Dear Mr. Sommer:

This is in response to your letter dated December 3, 2003, to the Food and Drug Administration (FDA) regarding the use of filtered milk in standardized cheeses, particularly Swiss cheese. You stated that it has been recently brought to your attention that there is a question concerning the use of filtered milk in Swiss cheese. You provided some data from trials conducted at the Center for Dairy Research (CDR) and maintained that these data and results of other studies conducted by CDR demonstrate that the composition and sensory characteristics of Swiss cheese made with milk that is supplemented with filtered milk are not significantly different from Swiss cheese made with only milk. In fact, you stated the flavor of Swiss cheese made using filtered milk was superior to that of the cheese made without using filtered milk. You further stated that the manufacturing procedure for making Swiss cheese using filtered milk is essentially the same as the standard "make" procedure used in the industry.

We thank you for your interest in this issue and for providing us with the information from your trials. As you may be aware, FDA has received two petitions, one from the American Dairy Products Institute (the ADPI petition; Docket No. 99P-5198/CP 1) and another filed jointly by the National Cheese Institute (NCI), the Grocery Manufacturers of America, and the National Food Processors Association (the NCI petition; 00P-0586/CP 2), requesting the amendment of Title 21 Code of Federal Regulations section 133.3 to include fluid filtered milk in the definition of milk and nonfat milk.

FDA has reviewed the ADPI petition and concluded that it did not present reasonable grounds to support the requested amendments. However, because the issues raised in the ADPI petition are clearly covered under the NCI petition, FDA closed the ADPI petition and converted it to a comment to the NCI petition. ADPI was informed of FDA's action in a letter dated February 26, 2003.

FDA also conducted a review of the NCI petition and the issues surrounding the use of fluid filtered milk in standardized cheeses and related cheese products. The development of a proposal to amend section 133.3 to provide for the use of fluid ultrafiltered milk in standardized cheeses and related cheese products was an A-list activity in FY2003 Center for

00P-0586

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Food Safety and Applied Nutrition's Program Priorities, and is likely to be a priority during FY2004. Accordingly, we are making progress on this issue. We encourage you and any food manufacturers you may collaborate with to provide comments on our proposed amendments when the proposed rule is published in the Federal Register. We have forwarded your letter to the Division of Dockets Management for inclusion in Docket No. 00P-0586. Please be assured that we will consider all comments received before making a final decision on this issue.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,

Ritu Nalubola

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December 3, 2003

Ms. Felicia B. Satchell, Director
Division of Food Labeling and Standards
Office of Nutritional Products, Labeling and Dietary Supplements-HFS-820
CFSAN/FDA
5100 Paint Branch Parkway
College Park, MD 20740

Dear Ms. Satchell:

I have been given your name as the lead contact within FDA regarding the use of Filtered Milk in standardized cheeses.

The Wisconsin Center for Dairy Research (CDR), established in 1986 and located on the campus of the University of Wisconsin in Madison, Wisconsin, is recognized by the United States dairy industry as the leading dairy research center in the U.S. and is recognized worldwide. As stated in our mission statement, one of our primary goals is to conduct strategic dairy industry research and to provide a link between the CDR, University faculty, staff, students and the dairy and food industries in order to address key issues and provide for the transfer of technology and the communication of information.

The CDR has been aware for some time of the interest by industry to use filtered milks in the making of cheeses, both standardized and non-standardized. Because of this, the CDR has conducted extensive research into the use of filtered milk in the manufacture of a number of cheese varieties over the last few years.

Recently it has been brought to our attention that there is a question concerning the use of filtered milks in the manufacture of Swiss cheese. Swiss cheese is one of the cheese varieties that the CDR has done significant work on. In total, we have performed 3 separate trials on the use of filtered milks in the manufacture of Swiss cheese, totaling 22 vats of cheese, 6 control vats without filtered milk and 16 experimental vats containing filtered milk.

The manufacturing procedure used for the experimental vats was essentially the same as that used for control vats and in essence represents a typical Swiss cheese make procedure as used by industry. All vats were sampled and extensively tested for composition in addition to other analyses not typically performed in industry such as sugar, ash, calcium, and nitrogen balances and fat balances in cheese and whey. Additionally, all vats of cheese were evaluated by a group of experienced cheese panelists for overall flavor and texture characteristics at regular time intervals until the Swiss cheese reached an age of 9 months.

The data in the following table represents mean and range data accumulated from the manufacture of Swiss cheese both with and without fortification with filtered milks:

	Standard Swiss	**UF Fortified Swiss**
pH	5.09 (range 5.05-5.12)	5.09 (range 4.93-5.14)
Fat %	29.67 (range 28.68-30.24)	29.92 (range 28.68-30.88)
Moisture %	38.59 (range 37.91-39.78)	38.36 (range 37.18-40.15)
Fat % of Solids	48.4 (range 47.6-49.1)	48.5 (range 47.9-50.1)

These data would indicate that there is no significant compositional difference between standard Swiss cheese and Swiss cheese made with milk fortified with filtered milks. Additionally, all vats of cheese conformed to the compositional standards found in the U.S. standards of identity 21 CFR 133.195 Swiss and emmentaler cheese. Also, the composition of these cheeses are very typical compared to that which we see in industry samples submitted for analysis.

Additionally, in our extensive sensory evaluation of the 22 vats of Swiss cheese done periodically over a period of 9 months of aging we found no significant difference between the flavors and textures of standard Swiss cheese and UF fortified Swiss cheese. In fact, in quite a number of vats the flavor of the fortified Swiss cheese was found to be superior to that of the standard Swiss cheese. Moreover, the eye development in UF fortified Swiss cheese was as good as that found in the standard Swiss.

In conclusion, experimental work done at the Wisconsin Center for Dairy Research on the use of filtered milks in the fortification of cheese milks for the manufacture of Swiss cheese has shown that there are no significant differences in the composition or the sensory qualities of Swiss cheese made with cheesemilk fortified with filtered milks as compared to Swiss cheese made without any fortification with filtered milks.

I hope you find this information useful and informative. Please feel free to contact me with any questions you may have.

Sincerely,

Wisconsin Center for Dairy Research

Dean A. Sommer

Dean A. Sommer
Cheese and Food Technologist

cc: Rusty Bishop – WI-CDR
Robert Fassbender – North American Milk Products
Allen Sayler - IDFA